

**REMARKS**

Claims 1-32 are pending in this application. Claims 1, 7, 13, 19, 25, and 26 have been amended without prejudice or acquiescence in order to advance prosecution of the instant application. Support for the claim amendments may be found on page 14, lines 5-7 and 16-17, and in original claim 27. The issues outstanding in the instant application are as follows:

- Claims 21-24 are objected to as being dependent on a rejected claim base.
- Claim 26 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.
- Claims 1, 2, 6, 13, 14, 18, 19, 20, 25-28, and 32 have been rejected under 35 U.S.C. § 102(b)/103(a) as allegedly being anticipated by and/or obvious over CN 1210695.
- Claims 1-20, and 25-32 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over RO 87637 in view of CN 1210695 and Remington's.

**I. Claim objections**

The Examiner has objected to claims 21-24 as being dependent on a rejected claim base, but otherwise allowable. Applicants maintain that claims 21-24 are dependent on an allowable claim base.

**II. 112 second paragraph rejection**

The Examiner has rejected claim 26 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claim 26 has been amended, and is not indefinite. Support for the amendment to claim 26 may be found in original claim 27, which indicates administration to a mammal. Applicants respectfully request withdrawal of the 35 U.S.C. § 112, second paragraph rejection.

**III. 102(b)/103(a) rejection**

The Examiner has rejected claims 1, 2, 6, 13, 14, 18, 19, 20, 25-28, and 32 under 35 U.S.C. § 102(b)/103(a) as allegedly being anticipated by and/or obvious over CN 1210695. Applicants respectfully traverse.

A claim is anticipated only if each and every element as set forth in the claim is found either expressly or is inherently described in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) (emphasis added). “The identical invention must be shown in as complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "

CN 1210695 teaches drinking water with calcium glutarate in concentrations of 10-1,000mg/L. Applicants teach a method of orally administering to a person in need thereof a quantity of a medicinal composition of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract and inhibit phosphorous absorption. Applicants also teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract.

Applicants teach a method of inhibiting phosphorous absorption in the gastrointestinal tract by administration of an effective amount of calcium glutarate. CN 1210695 teaches drinking water supplemented with calcium salts for nutritional value. CN 1210695 does not teach a method of inhibiting phosphorous absorption in the gastrointestinal tract. As CN 1210695 does not teach all the limitations of claim 1, namely of administration of sufficient amounts of calcium glutarate to inhibit absorption of phosphorous in the gastrointestinal tract, there is no anticipation of claims directed towards methods of inhibiting gastrointestinal absorption of phosphorous.

Furthermore, drinking water formulations comprising calcium salts taught by the CN 1210695 are nonequivalent to a pharmaceutical or medicinal composition which comprises a single dose of calcium glutarate, as the single dose of the pharmaceutical or medicinal composition is, by definition, intended to be consumed within a limited time period.

Drinking water as taught by CN 1210695 that is enriched by calcium salts has no limitations indicating that consumption of any particular serving, or dose, is required. There is simply no teaching in CN 1210695 of what consumption levels of drinking water are required. Also, not only are levels of consumption not described, there is no teaching of single dose consumption of any amount of the calcium salt-enriched drinking water.

There is no explicit or implicit suggestion in the reference that it would be desirable to modify it in such a manner as to yield Applicants' invention. Thus, the reference is insufficient to support a *prima facie* case of obviousness. In light of the above arguments, Applicants respectfully request withdrawal of the 102(b)/103(a) rejection of claims 1, 2, 6, 13, 14, 18, 19, 20, 25-28, and 32.

#### **IV. 103(a) rejection**

The Examiner has rejected claims 1-20, and 25-32, under 35 U.S.C. § 103(a) as allegedly being obvious over RO 87637 in view of CN 1210695 and Remington's. Applicants respectfully traverse.

##### **1. References lack motivation to combine**

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A statement that modifications of the prior art to meet the claimed invention would have been " 'well within the ordinary skill of the art at the time the claimed invention was made' " because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to

have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

The Examiner has not pointed to any explicit or implicit suggestion in the prior art to combine the references, and has merely made the statement that the combination would have been well within the skill of one with ordinary skill in the art. Without a motivation to combine the references, Examiner has failed to present a *prima facie* case of obviousness.

RO 87637A teaches medicinal composition containing multiple calcium salts, including calcium glutarate, calcium lactate, and calcium carbonate ( $\text{CaCO}_3$ ). Remington's teaches methods of preparing pharmaceutical dosage forms, and CN 1210695 teaches calcium glutarate mineralized drinking water.

Applicants teach a methods of inhibiting phosphorous absorption and compositions containing calcium glutarate in sufficient amounts for binding phosphorous in the gastrointestinal tract. On page 16, lines 13-15, of the specification, Applicants specifically teach away from calcium glutarate compositions containing calcium lactate, citrate, and carbonate. Applicants state that the presence of additional calcium salts in a composition neutralizes the gastric juice and inhibits the solubility of other calcium salts.

The combination of RO 87637A, CN 1210695, and Remington's teaches compositions containing multiple calcium salts, including calcium carbonate and calcium lactate. Such compositions as created by the modification of the references would influence the bioavailability of a composition also containing calcium glutarate. Although calcium glutarate is a highly soluble compound that is bioavailable in, for example, elderly patients with impaired gastric acid production, there is no motivation to create a composition with multiple calcium salts that would serve to neutralize the gastric environment, thus causing the possible need for an increased calcium glutarate dose. In such a situation, the additional calcium salts would be inhibiting the action of calcium glutarate. As such, there is no motivation to combine the cited references and they are insufficient to support a *prima facie* case of obviousness.

2. Combination of the references does not yield Applicants' invention

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

RO 87637A teaches medicinal composition containing multiple calcium salts, including calcium glutarate, calcium lactate, and calcium carbonate ( $\text{CaCO}_3$ ). Remington's teaches methods of preparing pharmaceutical dosage forms, and CN 1210695 teaches calcium glutarate mineralized drinking water.

Applicants teach a method of orally administering to a person in need thereof a quantity of a medicinal composition of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract and inhibit phosphorous absorption. Applicants also teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract.

The combined references do not teach a method of orally administering to a person in need thereof a quantity of a medicinal composition of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract and inhibit phosphorous absorption. The combined references do not teach single dose compositions and compounds of calcium glutarate sufficient to bind with phosphorous in the gastrointestinal tract.

Thus, as the combination of the references do not teach all limitations of the claimed invention, and as there is no motivation to combine the cited references, claims 1-20, and 25-32 are nonobvious. In light of the above arguments, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. According, the Examiner is respectfully requested to pass this application to issue.

Enclosed herewith is a petition for a one month extension of time and a check for \$55. Applicant believes no additional fee is due with this response. However, if a fee is due,


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please charge our Deposit Account No. 06-2375, under Order No. HO-P02490US0 from which the undersigned is authorized to draw.

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Respectfully submitted,

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